NUCLEAR REACTOR INSPECTION PROGRAM
EARLY SITE PERMIT

2501-01 PURPOSE

The Early Site Permit (ESP) inspection program establishes guidance for NRC inspection activities directed towards an ESP application, its review, and the related applicant activities governed by NRC regulations. The program is applicable to the applicant and their consultants, and to all activities related to NRC regulations. Specifically, the applicable principal regulations for this phase are those described by 10 CFR Part 52, 10 CFR Part 50 Appendix B and 10 CFR Part 100 (see Section 05.05 below). The ESP phase is implemented when the NRC receives formal notification under 10 CFR Part 52 of an applicant's intention to apply for an ESP. It continues until the ESP expires after 20 years or a combined operating license or construction permit is issued (See Figure 1).

Where the performance and/or surveillance of activities associated with the ESP phase have been contracted to other organizations, these instructions are applicable to the organizations conducting the activities for the applicant organization.

2501-02 OBJECTIVES

The principal objective of the ESP phase is to verify that the ESP application meets the requirements specified in 10 CFR Part 52 and is of a quality suitable for docketing. Additional objectives are to (1) reduce unnecessary regulatory burden, and optimize the efficiency and effectiveness of docketing, (2) explain to the public the contents of an ESP application, and the opportunities for public intervention, (3) explain the NRC licensing process, and (4) ascertain whether the appropriate elements and standards to assure quality are being applied to ongoing project activities, as will be required during the NRC post-application review.

To achieve these objectives, substantial emphasis will be placed on verifying the quality and accuracy of data collected and the analysis and the evaluation of information used in support of the application. Where applicable elements which assure quality cannot be applied or there are no applicable requirements, inspection and audits will verify that data is collected using industry accepted methodologies such as NUREGS or other guidance listed in the NRC Standard Review Plan (NUREG 0800).

2501-03 DEFINITIONS

Definitions of terms used in this inspection program are as follows:

03.01 Audit. An applicant/contractor activity to determine through investigation the adequacy of/and adherence to, established procedures, instructions, specifications, codes, and other applicable contractual and licensing requirements, and the effectiveness of implementation.

03.02 Contractor. Any organization under contract to furnish items or services to an organization operating under the requirements of Appendix B of 10 CFR Part 50 or the commitments made in the application. It includes the terms Consultant, Vendor, Supplier, Fabricator, Constructor, and subtier levels of these, where appropriate.

03.03 Documentation. Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

03.04 Inspection. An NRC activity consisting of examination, observation or measurements to determine the conformance with requirements and/or standards.

03.05 NRC QA Guidance. Guidance endorsed by NRC through issuance of regulatory guides or national standard documents which discuss acceptable methods of implementing portions of 10 CFR 50, Appendix B QA program requirements.

03.06 Objective Evidence. Any direct observation or documented statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements, or tests which can be verified.

03.07 Quality Assurance. Quality Assurance (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service. QA includes quality control.

03.08 Quality Assurance Manual. The collection of internal procedures and instructions established by each organization delegated QA Program authority and whose objective is to assure acceptable implementation of the QA Program.

03.09 Quality Control. Quality control (QC) comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

03.10 Quality Assurance Program/QA Commitments. The terms QA program and QA commitments relate to the description of the QA program, or any part thereof, as required by 10 CFR 50.34(a)(7).

03.11 The Tendered/Docketed Application. As used by this instruction, the tendered application consist of the ESP application, 10 CFR 52.17 (a) - (c) general information; 10 CFR 50.33 a - d, information required by 50.34(a)(12) and (b)(10); and to the extent approval of emergency plans is sought under paragraph (b)(2) (ii) of 10 CFR Part 52, the 10 CFR 51.45 and Part 51.50, Environmental Report.

Where the term docketing is used by this instruction it refers to the docketing of the ESP application.

2501-04 RESPONSIBILITIES AND AUTHORITIES

The Commission has the overall responsibility to make a determination regarding the acceptability of the ESP application. The applicable Regional Administrator has the responsibility to make a recommendation to the Director, Office of Nuclear Reactor Regulation, regarding denial or approval of the ESP application (see Enclosure 2).

The Director, Division of Inspection and Program Management has the responsibility to review and make a determination regarding the acceptability of the QA program description document if presented with the applicant's application and for ascertaining whether the applicant has established and executed acceptable QA controls.

The Director, New Reactor Licensing Project Office, has the responsibility to make a determination regarding the acceptability of the technical information in support of the ESP application and to determine whether to docket the application.

2501-05 DISCUSSION

05.01 Pre-Application. During the pre-application phase the NRC primarily gathers information regarding the quality of site suitability data and environmental data collected in support of the application.

Prior to the application, and as early as possible after notification of the applicant's intention to submit an ESP, the NRC will conduct meetings with the applicant to (1) meet the primary contacts for the various technical disciplines, (2) review the applicant's schedule for collection of data, and related ESP activities, (3) arrange for observation of data collection methodology, (4) arrange for a preliminary walk-down of the prospective site and (5) review the applicant's QA controls/program description.

Additionally, the NRC will coordinate schedules with the applicant and gather information in preparation for public meetings, schedule public meetings to introduce the local community to the NRC licensing process, and arrange meetings with state and local officials.

The pre-application QA program review will be performed as early as possible before the tendering of an ESP application. Representatives from the Office of Nuclear Reactor Regulation (NRR) and the respective region will meet with the applicant's representatives approximately 6–12 months prior to tendering the ESP application. A clear understanding of what is expected in a QA Program Description, the accepted methodologies for data collection, and the critical parameters the NRC expects to observe relative to the applicant's schedule should be discussed. The pre-application review will place particular emphasis on the areas of organization, the QA program, document control, and methodologies for data collection, analysis, and evaluation. Departures from accepted QA principles or deviations from accepted industry standards may require independent evaluations, request for additional information, and additional communications with the applicant, thus extending the NRC review and evaluation process. Significant deviations from accepted industry standards without justification may result in the denial of the ESP application.

Additionally, the ESP inspection program provides for a review of applicant oversight of contracted activities and inspection of those activities. The direct inspection of contractor work activities may be performed, as necessary, to ensure the effective control of all work and the proper implementation of the required elements of the QA program.

05.02 Post-Application Review. Once received, the application will be reviewed according to 10 CFR Part 50 Appendix B, as required by 10 CFR Part 52.18 (see 03.06 below). During the post-application period (See Figure 1), inspections are conducted primarily to support testimony for the Atomic Safety and Licensing Board (ASLB) hearing required by 10 CFR 52.21. Based on the information provided by the applicant and the results of the inspections, safety evaluation reports (SER)s will be issued and the ASLB hearing will be conducted prior to making the determination whether to grant the ESP.

05.03 Inspections. Inspections will be accomplished by the regional office having geographical jurisdiction with technical support from NRR. Inspections will be lead by the responsible region after coordinating the effort with the responsible NRR PM. Technical support will be provided by various divisions within NRR as requested by the PM. The technical staff will evaluate the applicant's methodologies for data collection using the guidance provided in the NRC Standard Review Plan (NUREG-0800), the NRC Environmental Standard Review Plan, and ASTM Standards where applicable. Inspections will be consolidated to minimize impact on the applicant. Within 5 days of the conclusion of the inspection, the NRR technical staff and/or its contractors will forward their findings to the inspection team leader for integration into a trip report.

Site visits and meetings conducted exclusively by the NRR Project Manager or NRR technical staff should as a minimum be documented in a trip report with the cognizant regional management on distribution.

ESP Phase Inspection Guidance, Enclosure 1 to MC-2501, provides guidance which may be applicable during inspections, audits, or site visits.

05.04 Enforcement. Enforcement actions associated with an ESP application are not anticipated in the pre-application phase. However, as stated in Part 52.21, an early site permit is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR Part 2 applicable to construction permits. The information submitted with the application will become subject to NRC regulations including enforcement actions for willful wrongdoings or fraudulent information.

05.05 Quality Assurance. 10 CFR 52.18 requires that applications filed under Part 52 be reviewed according to the applicable standards set out in 10 CFR Part 50 and its appendices and Part 100 as they apply to applications for construction permits for nuclear power plants. Section 50.55, "Conditions of a Construction Permit" states in (f)(1) that each construction permit holder subject to the QA criteria in appendix B shall implement, pursuant to 50.34(a) a QA plan. 10 CFR Part 50.34 states that an applicant is required to submit a QA program description discussing how the applicable requirements of Appendix B will be satisfied. Accordingly, those portions of the ESP application which are applicable to the requirements of 10 CFR Part 50 Appendix B will be inspected and reviewed pursuant to Appendix B (and if provided with the ESP application), the QA program description. The quality and pedigree associated with those parts of the ESP application not applicable to Appendix B will be reviewed to recognized industry codes and standards.

Notwithstanding the above, with the initial tendering of the ESP application and until the completion of reviews of the application, it is recognized that certain aspects of the QA commitments initially submitted may not fully describe the 18 criteria of Appendix B, because not all criteria are applicable to ESP activities. However, the application should provide an adequate basis for evaluation of the acceptability of the QA program implementation. Data collected using methodologies fully complying with a QA program will expedite the inspection, evaluation, and licensing process.

The inspector will review the description of the QA program provided in the application and assess the consistency of the implemented instructions and procedures with the QA Program. Inspections

and the evaluation and resolution of identified problem areas should be accomplished consistent with the referenced guidance in Enclosure 1. In no case should NRC inspectors inform the applicant of what effect identified QA problem areas might have on a docketing decision prior to discussion with headquarters.

a. Quality Assurance Applicability. The applicable criteria of 10 CFR 50 Appendix B are those criteria which can directly relate to the pedigree or genesis of any safety- related or risk-significant structure, system, or component (SSC). For example, for an ESP application, Appendix B criteria must be applied to the methodology for data collection, analysis, and evaluation for soil composition, geology, hydrology, and seismology determinations for the foundations of safety-related SSCs. When information is received from organizations like the Census Bureau or the National Oceanic and Atmospheric Administration (NOAA) ,etc., controlling the records received from the organization and the evaluation and analysis, and storage of the records is considered "applicable" and subject to Appendix B criteria.

   All information submitted with the ESP application will be reviewed and is subject to Appendix B controls. Inspection will be limited to only the information presented in the application and performed on a sampling basis to provide added confidence that the application contents is in conformance with the regulations.

b. NRC Process Relating to Inspection of QA Program. The NRC process relating to inspection of the QA program implementation and documentation of findings is as follows:

   1. As part of the inspection preparation, prior to conducting the program implementation inspection at the offices of the applicable organization, the review of the applicable elements of the QA program shall be performed in the regional office. Findings shall not be formally documented in an inspection report until after conduct of the QA program implementation inspection at the applicant/contractor offices (and at the site, as appropriate).

   2. Significant findings relating to the QA program may be forwarded to NRR for review and resolution with DIPM/IEHB at any time during the performance of the inspection activity.

05.06 Limited Work Authorization (LWA). If an early site permit contains a site redress plan, the holder of the permit may perform the activities at the site allowed by 10 CFR 50.10(e)(1). A limited work authorization under § 50.10(e) is informally termed LWA-1. Under 10 CFR 50.10(e)(1), the Director of NRR may authorize site preparation work, installation of temporary construction support facilities, excavation for nuclear and non-nuclear facilities, construction of service facilities and construction of structures, systems and components which do not prevent, or mitigate the consequences of postulated accidents. This may include the extension of previously permitted activities subject to 10 CFR Part 50, Appendix B, such as the continuance of site exploration and the receipt and storage of items resulting from procurement permitted prior to issuance of the construction permit. An LWA-1 may be granted only after the ASLB has made all of the National Environmental Policy Act (NEPA) findings required by 10 CFR Part 51 for the issuance of a construction permit and has determined that there is reasonable assurance that the proposed site is a suitable location for a nuclear power reactor of the general size and type proposed from a

radiological health and safety standpoint. In each case the LWA-1 will clarify which of the requested activities may be conducted at the site and the conditions that must be met. If the LWA-1 is granted, special precautions should taken if an existing operating plant is in close proximity as overhead power lines may be impacted by cranes, and earth moving activities may impact flooding of the existing facility etc.

END

Enclosures:

1. INSPECTION GUIDANCE

2. SAMPLE LETTER

3. EARLY SITE PERMIT TIME-LINE

ENCLOSURE 1

INSPECTION GUIDANCE

INSPECTION PROCEDURE	INSPECTION GUIDANCE
30001	NRC/Applicant Corp. Management Meeting consistent with the date set by NRR
35002	Applicant Early QA Meeting
35003	QA manual review
35004	Initial Pre-Docket QA Inspection
35006	Pre-docketing Assessment and Conclusions
35008	NRR/ NRC/Applicant Meeting - Substantive QA Findings
35016	Initial ESP QA Inspection
35020	Audit of Applicant's Surveillance of Contractor QA/QC Activities (if required)
35022	NRC ESP Summary SER Position Statement
35024	Followup ESP SER or SER Supplement QA Inspection (if required)
35026	NRC ESP Summary SER Position Statement Supplement (if required)
45051	Geo-Technical Foundation Activities procedure Review

INSPECTION PROCEDURE	INSPECTION GUIDANCE
45053	Site Preparation - Observation of Work Activities
45055	Geo-Technical Foundation Record Review
80210	Environmental Protection Initial Inspection
94700	Participation in ACRS Meetings (if required)
94010	NRC Testimony for ASLB or ASLAB Hearings (if required)

ENCLOSURE 2

SAMPLE LETTER

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION XX, Address

Memorandum To:_____, Director
Office of Nuclear Reactor Regulation

FROM: _____,
Regional Administrator

SUBJECT: (Site name) EARLY SITE PERMIT APPLICATION

(XXX) Corporation , by letter dated (XXXXX) , requested an Early Site Permit (ESP) for (XXX) Nuclear Station, Units (X) in accordance with Title 10 of the. Code of Federal Regulations Part 52 . We have completed our inspections in accordance with the guidance contained in Manual Chapter (MC) 2501 and in close coordination with the Office of Nuclear Reactor Regulation. The inspections verified that (XXXX) has implemented programs in conformance with the descriptions contained in (XXXX' s) application.

Additionally, the inspections compared statements in the safety evaluation report with (XXXX's) implementation in the field confirming the accuracy of assumptions used by the Office of Nuclear Reactor Regulation (NRR) to form technical positions. Details of the scope of our inspections and results are contained in the following Inspection Trip Reports (XXX) dated (XXXXX)....

Based on the results of our inspection efforts, we have determined that (Company's) programs and activities related to the ESP at (Company) have been completed in agreement with docketed commitments and regulatory requirements. Within the above inspection scope, we have determined that (Company) has met the applicable criteria for site suitability, emergency preparedness and environmental impact. We, therefore, conclude there is reasonable assurance that (Company) has provided an adequate foundation for the granting of an early site permit.

Early Site Permit Timeline

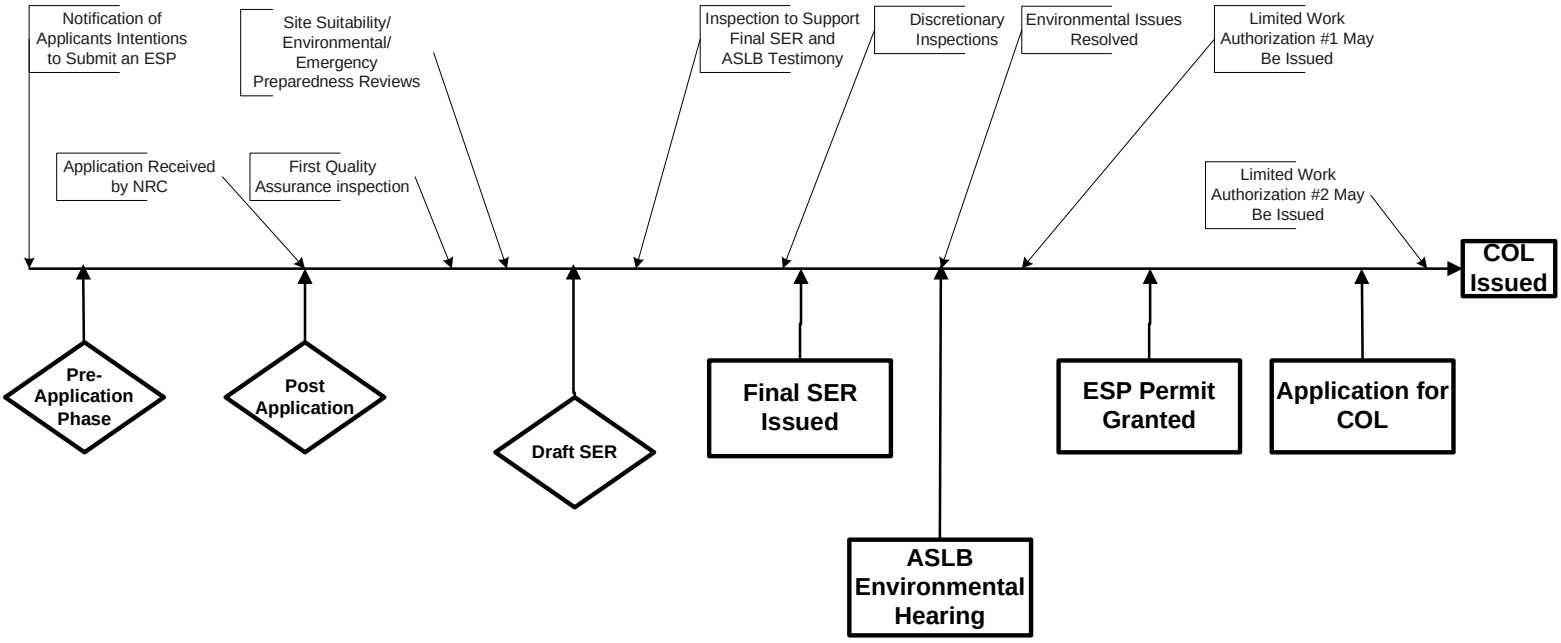

Figure 1